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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,953	10/03/2000	Hiroshi Kubota	113918,401	7343

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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/26/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/678,953

Applicant(s)

KUBOTA ET AL.

Examiner

Thaian N. Ton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment, filed 7/8/02, Paper No. 14 has been entered. Claims 25 and 26 have been cancelled. Claims 1, 3, 5 and 15 have been amended.

Claims 1-24 are pending. Claims 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11 (Filed 12/4/01).

Claims 1-20 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 1-20, 25 and 26 is rendered moot in view of Applicants' cancellation of claims 25 and 26.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The prior rejection of claims 3 and 14 with regard to the recitation of the term, "weakly" is maintained. The claims are further unclear because they recite the term "dull positive" response to immunostaining. In particular, the claims as amended state that weakly expressed is "indicated by a dull positive response to immunostaining," however, it is not clear what the metes and bounds of weak expression are, in particular, because weak expression is defined by "dull positive" and the term "dull" is not specifically defined. How dull of a response is required for an antigen to be considered weakly expressed? As such, the metes and bounds of "dull" and "weakly" are not clear. Clarification and/or amendment is requested. Claims 15-20 depend from claim 14.

Claim 5, as written, is unclear because the metes and bounds of the comparison between hepatic progenitors to mature parenchymal cells is not specifically defined. For example, do hepatic progenitors from one species of animal have a numerically less sidescatter value than that of mature parenchymal cells of another species of animal? Clarification and/or amendment is requested.

Claim 15, as written, is unclear. The claim recites that the hepatic progenitors or their progeny, or a combination are derived from endoderm or bone

marrow, however, it is unclear what the term "derived from" encompasses because the metes and bounds of the term are not specifically defined.

The prior rejection of claim 14 for the recitation of the term, "higher" in part (b) of the claim is maintained. The claim as amended now states that the hepatic progenitor cells exhibit a "numerically higher" sidescatter value than the side scatter value of non-parenchymal cells. The claim is unclear because the metes and bounds of the comparison between the hepatic progenitor cells and the non-parenchymal cells is not specifically defined. For example, are the hepatic progenitors from a different animal species than that of the non-parenchymal cells? Clarification and/or amendment is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Haruna *et al.* [Hepatology, 23:476-481, 1996, cited by Applicant on IDS filed 8/31/01, Paper No. 8].

The claims are directed to compositions comprising bipotent hepatic progenitor cells which express at least one ICAM antigen and do not express MHC

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class 1a antigen, wherein the bipotent hepatic progenitors have the capacity to differentiate.

Note that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Further, it is noted that, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The specification teaches that the compositions of bipotent hepatic progenitor cells of the claimed invention were obtained from fetal livers [see pp. 14-15 of the specification]. As such, the claimed properties such as the expression of an ICAM antigen and the lack of expression of MHC class Ia antigen [see claim 1], that the hepatic progenitor cells express at least one MHC class Ib antigen [see claim 2], and that the hepatic progenitors have a sidescatter value determined by flow cytometry

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which is numerically less than the sidescatter value of mature parenchymal cells [see claim 5, for example], are inherent properties of any bipotent progenitor cells. As stated in the preceding paragraphs, a chemical composition and its properties are inseparable. As such, Haruna *et al.* teach the isolation and identification of of bipotent liver progenitor cells isolated from fetal livers. As Haruna's cells are disclosed to be isolated from human fetal livers, as are those cells claimed by Applicant, they would reasonably be expected to have the same physical and biochemical properties. Furthermore, it is noted that the limitation "composition" as broadly written, reads on an intact liver.

Accordingly, Haruna *et al.* anticipate the claimed invention.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)872-9306.

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